

Successful Removal of Quetiapine From a Correctional Formulary

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The abuse of medications in prison is a phenomenon well known among correctional health care professionals, and quetiapine has emerged as a drug of abuse in these settings. Considering the risks of abuse and diversion and the high cost compared with effective alternative antipsychotic medications, the New Jersey Department of Corrections (NJDOC) Pharmacy and Therapeutics Committee voted to remove quetiapine from the formulary. In a retrospective chart review, clinically relevant outcome measures were evaluated in patients prescribed quetiapine at the time of this change. Psychiatrists attempted to stop the quetiapine in 63.4 percent of the cases and were successful (not requiring continuation or restarting of the medicine) 95.7 percent of the time. There were no statistically significant differences in the number of patients who needed a higher level of care, days in a higher level of care, number of patients needing constant (e.g., suicide) watch, days on constant watch, suicidal behavior, or disciplinary charges when the subjects in whom an attempt to discontinue quetiapine was made was compared with those in whom it was continued. In 44.7 percent of cases in which an attempt was made to stop quetiapine (and in 28.3% of cases in the entire NJDOC population as of January 2009), no antipsychotic medication was needed to manage the patients during the study period. This study supports the decision to remove quetiapine from the NJDOC formulary.

J Am Acad Psychiatry Law 40:502–8, 2012

Substance abuse and dependence are common problems among incarcerated individuals. In 2006, the U.S. Department of Justice estimated that more than two-thirds of jail inmates and one-half of prison inmates met the criteria for a substance-related disorder. The prevalence of substance abuse was higher in inmates who also self-reported a history of mental illness.¹ Even while incarcerated, many inmates continue to abuse substances. Before an enhanced interdiction program was established in the Pennsylvania Department of Corrections, 7.8 percent of inmates were confirmed by hair analysis to have used an illegal drug within the prior 90 days.²

The abuse of prescribed medications in prison has been described^{3–6} and is a phenomenon well known

by correctional health care professionals. Prescribed medications are easier for inmates to obtain, given that they are legal and already present within correctional institutions. With the exception of benzodiazepines and barbiturates, prescribed medications in a correctional setting are typically not included in screening tests for drugs of abuse.

Quetiapine fumarate (Seroquel) is an atypical antipsychotic medication, approved by the U.S. Food and Drug Administration (FDA) for the treatment of schizophrenia, bipolar mania, and bipolar depression and as an adjunctive treatment for major depressive disorder.⁷ It is clinically well known for its sedative properties. Several studies suggest that it is effective for generalized anxiety disorder.⁸ In 2008, AstraZeneca submitted a supplemental New Drug Application to the FDA seeking approval of the drug for treatment of generalized anxiety disorder.⁹ At the time of the study, quetiapine was approved only for the treatment of schizophrenia and bipolar disorder.¹⁰ Psychiatrists may prescribe it off label for a wide variety of indications. For example, we have observed psychiatrists inappropriately prescribing it in low doses for the treatment of insomnia in prison.¹¹

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Disclosures of financial or other potential conflicts of interest: None.

Quetiapine has emerged as a drug of abuse, known colloquially as Quell, Suzie Q, Q, Squirrel, or Baby Heroin.^{6,12} It has been cited in rap lyrics that describe its use for recreational purposes.^{13,14} Numerous case reports have been published documenting the misuse of, abuse of, and even dependence on quetiapine in the community. Feigning or exaggeration of serious psychiatric symptoms; preferential use despite the effectiveness of an alternative agent; use to mitigate the symptoms of withdrawal from benzodiazepines and illicit substances; tolerance, withdrawal, and self-dosing in users; combination with illicit substances to achieve a hallucinatory effect; procurement from multiple sources; theft; and sale have all been described in the literature.¹⁵ Some of the earliest case reports in this regard involved prisoners, including descriptions of both intranasal⁴ and intravenous¹⁶ abuse. The sedative and anxiolytic properties of quetiapine are hypothesized by several authors to be the reason for the drug's propensity for abuse.

Atypical antipsychotics, including quetiapine, have been implicated in causing metabolic derangements associated with diabetes and cardiovascular disease. Quetiapine is considered to carry a moderate risk of metabolic complications.¹⁷ Like any antipsychotic, it carries the risks of potentially permanent (e.g., tardive dyskinesia) and even fatal (e.g., neuroleptic malignant syndrome) complications and side effects.⁷

In the CATIE (Clinical Antipsychotic Trials of Intervention Effectiveness) trial, quetiapine, risperidone, perphenazine, and ziprasidone were found to be of similar efficacy for schizophrenia in time to discontinuation.¹⁷ Despite the lack of therapeutic superiority of quetiapine, at the time of the writing of this article, it was more expensive than many antipsychotic medications. A month's supply of quetiapine costs more than 38 times as much as a month's supply of haloperidol. At a dose of 600 mg per day, quetiapine costs more than \$10,000 per patient-year.¹⁸ Institutional pharmaceutical pricing may be even more favorable toward generics when negotiated through a pharmacy vendor.

Despite the dramatic differences in cost between branded and generic medications, the contention that formulary changes can result in an overall reduction in costs has been called into question, stemming from the opinion that restrictive formularies will result in greater health care utilization.^{19,20} Increased

costs related to emergency mental health care were observed when Medicaid recipients' access to psychotropic medication was limited for a time in New Hampshire.²¹ Similarly, when olanzapine was removed from the Medicaid formulary in Florida, the cost of increased services (e.g., emergency room visits and hospitalization) largely offset the reduced payments for olanzapine.²²

The New Jersey Department of Corrections (NJDOC) has a medication formulary controlled by the Pharmacy and Therapeutics (P&T) Committee, on which representatives from NJDOC and University of Medicine and Dentistry of New Jersey–University Correctional HealthCare (UCHC) serve jointly. In 2008, quetiapine was listed on the NJDOC formulary. Based on the reasons cited in the prior paragraphs, the P&T Committee agreed, on January 23, 2009, to remove quetiapine from the NJDOC formulary. Quetiapine would remain available through a nonformulary approval process that requires the treating psychiatrist to document the clinical justification for this medicine as opposed to a formulary alternative.

The removal of quetiapine from the formulary was not taken lightly. Patients whose antipsychotic medications are discontinued may experience a relapse of psychotic symptoms.²³ When other correctional systems removed quetiapine from their formularies, inmates threatened lawsuits and suicide.⁵ Physicians have negative attitudes about medication formularies in general,²⁴ attitudes that have been passionately expressed to us by treating psychiatrists in our system.

For the purpose of following up this important formulary change, UCHC commissioned a review, initially intended as a quality assurance and performance improvement (PI) activity, to evaluate the clinical impact of removing quetiapine from the NJDOC formulary. The hypothesis was that removing quetiapine from the formulary would have little effect on important measures suggestive of clinical status and level of functioning.

Methods

Patients for whom quetiapine was prescribed at the onset of the formulary change were identified from data provided by Maxor National Pharmacy Services Corporation, the UCHC pharmacy vendor. The P&T committee gave 60 days' notice to prescribers before the formulary change. Treating psy-

chiatrists were instructed to submit paperwork to regional psychiatric supervisors when continuation of quetiapine was considered clinically necessary.

Several objective indicators of inmate patient functioning are readily determined from a simple chart review: residence in general population versus a prison mental health inpatient unit, constant (e.g., suicide) watches, and disciplinary charges. Nearly all NJDOC inmate patients with mental health needs receive treatment in the general population (GP). The criteria for inmate housing on a unit with a higher level of mental health services are primarily based on the inmate's functional capacity. The Transitional Care Unit (TCU) provides augmented mental health services for inmate patients expected to return to general population. The Residential Treatment Unit (RTU) is for the long-term care of chronically mentally ill individuals. The Stabilization Unit (SU) is for the management of inmate patients in crisis due to symptoms of a mental illness. Those inmate patients in crisis who are unable to stabilize within this system are referred to the Ann Klein Forensic Center (AKFC), New Jersey's maximum-security forensic psychiatric hospital.

Inmate patients assessed to be an imminent danger to self or others (e.g., suicide risk, homicide risk, or psychiatric decompensation) are placed on constant watch, a status requiring 24-hour surveillance by custody staff, housing in a constant-watch observation cell, limited access to items that could be used to injure self or others, and enhanced treatment services. Most inmates on constant watch have a Global Assessment of Functioning scale score less than 30, indicating at least some danger of harming self or others, the presence of psychotic symptoms that are considerably influencing the patient's behavior, or both.²⁵ Being on constant watch is not mutually exclusive with any level of care (GP/TCU/RTU/SU).

Disciplinary offenses sometimes indicate behavioral manifestations of psychiatric instability. Whenever an inmate under treatment for a mental illness receives a charge for an institutional infraction, except for the most minor offenses, a psychologist completes an evaluation to determine the inmate's competence for an administrative hearing and the influence of the inmate patient's mental illness on his behavior, if any. Each psychologist completing disciplinary evaluations receives didactic training on forensic assessments.

We retrospectively reviewed every electronic medical record (EMR) for patients identified as having been prescribed quetiapine as of January 23, 2009. We included records between January 23 and July 22, 2009 (the period 180 days after the formulary change). The PI team members reviewed the medical record problem list to determine the most relevant diagnosis for the prescription of quetiapine. The PI team members chose transfers to higher levels of care (i.e., upward transfers between GP, TCU/RTU, SU, and AKFC), constant watches, and disciplinary charges (excluding on-the-spot infractions that do not require a formal disciplinary hearing) as outcome measures. The actual dates of the higher levels of care and constant watches were recorded, to allow for calculation of days spent in these settings. The disciplinary evaluations were reviewed to determine the nature of the charge as violent (defined as assaults, fighting, threatening, or property destruction) and the psychologist's assessment as to whether a mental illness influenced the behavior in question. We similarly reviewed constant-watch records to identify incidents of actual harm incurred by the patient or others. The patients in whom an attempt to discontinue quetiapine was made were compared with patients in whom it was deliberately continued (an intent-to-treat methodology). For the patients whose quetiapine was actually discontinued, the 90 days after the date when the dose was first at zero were used to compare indicators of inmate patient functioning. When the quetiapine was never stopped, whether or not this was the psychiatrist's intent, we used the 90 days after the date of the formulary change.

With early results suggesting that this review had relevance beyond the NJDOC, the PI team agreed to reformulate the work as a research project. Approval was obtained from the NJDOC Departmental Research Review Board, University Correctional HealthCare, University Behavioral HealthCare, and the UMDNJ Robert Wood Johnson Medical School Institutional Review Board (IRB). Subsequent to IRB approval, identifying patient information was replaced with encrypted data from all study-related documentation, to protect confidentiality.

We used Fisher's exact test for comparing two binomial populations for true/false variables, such as whether the subject needed a higher level of care, constant watch, or disciplinary charges. We analyzed continuous variables (such as days in higher levels of

Table 1 Indications for Quetiapine Identified by Chart Review

Principal Listed Indication	Intent to Stop (<i>n</i> = 161)	%	Intent to Continue (<i>n</i> = 93)	%	<i>p</i> (Fisher's Exact Test)
Principal listed indication					
BPAD	49	30.4	27	29.0	.88
Schizoaffective disorder	39	24.2	24	25.8	.88
Major depressive disorder	10	6.2	3	3.2	.38
Posttraumatic stress disorder	10	6.2	0	0.0	.02*
Schizophrenia	9	5.6	8	8.6	.43
Impulse control disorder/IED	8	5.0	5	5.4	.55
Psychotic disorder NOS	6	3.7	7	7.5	.23
MDD with psychosis	6	3.7	3	3.2	1.00
Personality disorder	5	3.1	6	6.5	.33
Mood disorder NOS	4	2.5	5	5.4	.29
No active diagnosis	4	2.5	0	0.0	.30
Substance related	4	2.5	2	2.2	1.00
Anxiety, NOS	2	1.2	2	2.2	.63
Panic	1	0.6	0	0.0	1.00
Generalized anxiety disorder	1	0.6	0	0.0	1.00
Dysthymia	1	0.6	0	0.0	1.00
Obsessive compulsive disorder	1	0.6	0	0.0	1.00
Insomnia	1	0.6	0	0.0	1.00
Depressive disorder NOS	0	0.0	1	1.1	.37
Total	161	100.0	93	100.0	
FDA indication (strict)	58	36.0	35	37.6	.89
Non-FDA indication (strict)	103	64.0	58	62.4	1.00
Mood or psychotic disorder	124	77.0	77	82.8	.19
No mood or psychotic disorder	37	23.0	16	17.2	.33

NOS, not otherwise specified.

* $p < .05$.

care or days on constant watch) with the t-test for independent variables. Significance was set at $\alpha = .05$ and two-sided tests were used.

Results

At the end of January 2009, quetiapine was prescribed to 254 inmate patients, representing approximately eight percent of the inmates with a Mental Health Special Needs designation or more than one percent of the entire NJDOC inmate population. After the formulary change, an attempt to stop quetiapine was made in 161 (63.4%) of these cases. The attempt to stop succeeded (defined as no drug being prescribed) in 90.0 percent of the cases ($n = 161$) within 90 days of the formulary change and in 95.7 percent of the cases within 180 days. Restarting quetiapine was necessary in three (1.9%) cases, and in another four (2.5%) cases, the attempt to stop was never completed. Within the 180-day period following the formulary change included in the chart review, patients in whom an attempt was made to discontinue quetiapine had a dose of zero for a mean of 138.0 days and a median of 143.0 days. A post hoc review revealed that in two of the three cases requir-

ing a restart of quetiapine, the inmate patient had a chronic, serious mental illness, and quetiapine had been abruptly discontinued (transitioning from 400 mg to zero in one case and 300 mg to zero in the other).

Among the cases planned for discontinuation ($n = 161$), only 36.0 percent had been prescribed quetiapine for a then-current FDA indication (schizophrenia or bipolar disorder). When we broadened the scope of appropriate indications to include any psychotic or affective disorder, 23.0 percent of the inmates in cases planned for quetiapine discontinuation had been receiving it for an off-label indication. There were more cases of posttraumatic stress disorder among patients whose psychiatrists attempted to stop quetiapine compared with those whose psychiatrists continued it (10 vs. 0; $p = .02$); otherwise, there was no statistically significant differences between the groups in terms of specific diagnoses or when mood and psychotic disorders were considered in aggregate (Table 1). Alternative antipsychotic medications identified by the chart review are shown in the Figure 1. In 44.7 percent of the patients in whom an attempt was made to stop the

Figure: Alternative Antipsychotics Used in Place of Quetiapine

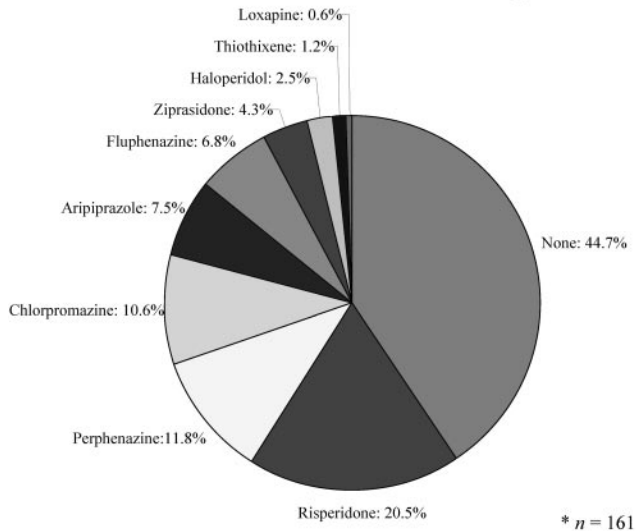


Figure 1. Alternative antipsychotics used in place of quetiapine.

quetiapine (and in 28.3% of the NJDOC population prescribed quetiapine as of January 2009; $n = 254$), no alternative antipsychotic medication was prescribed.

Psychiatrists opted to continue quetiapine in 93 (36.6%) cases. There were 92 non-formulary requests submitted in the first 90 days after the formulary change, although many of those were temporary requests to allow a taper. Requests were approved unconditionally in 44.6 percent of these cases, whereas in 4.3 percent, the request was refused outright. The average dose of quetiapine prescribed in disapproved requests was 137.5 mg per day, whereas the average dose for all quetiapine prescriptions at the time of the formulary change was 375 mg per day. The most frequent supervisory response to a nonformulary request for quetiapine ($n = 92$, 47.8%) was to approve it temporarily to allow sufficient time for a taper or a switch to an alternative medication, if appropriate. The reasons for continuation cited most often on approved nonformulary requests were the inmate's clinical stability on quetiapine (54.2%), the failure of other medication trials (35.6%), or imminent community release (8.5%).

Comparing the group in which a quetiapine discontinuation was attempted ($n = 161$; mean days for comparison, 85.5) with that in which it was continued ($n = 93$; mean days for comparison, 90.0), there were no statistically significant differences in the incidence of episodes of higher levels of care (respec-

tively, 9.9% vs. 7.5%; $p = .54$), mean days in higher levels of care (3.50 vs. 2.95; $p = .80$), incidence of episodes of constant watch (11.8% vs. 6.4%; $p = .18$), mean days on constant watch (0.75 vs. 0.57; $p = .70$), incidence of injuries toward self or others while on watch (3.1% vs. 3.2%; $p = .77$), incidence of incurring disciplinary charges (11.8% vs. 12.9%, $p = .75$), incidence of disciplinary charges for violent offenses (5.0% vs. 5.4%, $p = .78$), or incidence of disciplinary charges for violence assessed to have been influenced by a mental illness (0.6% vs. 2.1%, $p = .26$).

According to UCHC's pharmacy vendor, the cost associated with the prescription of quetiapine was reduced by \$1.1 million in 2009. Counting the cost of alternative antipsychotics when needed, the net annual saving was estimated to be \$846,240. Whether the quetiapine was continued or discontinued, none of these patients had a medical or psychiatric hospitalization during the follow-up period.

Discussion

To our knowledge, there are no reports in the published literature about the clinical effects of major formulary changes involving psychotropic medication in a prison system. Studies of the clinical effects of psychotropic formulary changes in general are few and are of limited relevance to the questions addressed in this work (e.g., Fillit et al.²⁶).

There were no patient deaths, no medical admissions for serious suicide attempts, and no crisis civil commitments to a community hospital after quetiapine was discontinued. There was no increase in violent offenses assessed to have been influenced by a mental illness by psychologists performing routine disciplinary evaluations. Furthermore, and perhaps our most important finding, there were no statistically significant changes in objective indicators of clinical functioning (such as transfers to higher levels of care, constant watch incidents, and disciplinary charges) when the charts of patients whose quetiapine was continued were compared with those in whom a discontinuation was attempted.

A key finding from our chart review was that, in 44.7 percent of cases ($n = 161$) involving an attempt to discontinue quetiapine and in 28.3 percent of all patients on quetiapine in the NJDOC at the end of January 2009 ($n = 254$), no antipsychotic medication was used to manage these patients at the com-

pletion of the study period. Once a decision was made to stop the quetiapine, failure to discontinue it or requests to restart it were uncommon occurrences. Some of these restarts may have been avoided by following the practice of gradually cross-tapering antipsychotic medications in individuals with serious mental illnesses.²⁷ Judging by the large proportion of nonformulary requests and approvals for tapering the medicine, the abrupt discontinuation of quetiapine by psychiatrists in our system was atypical.

When an alternative antipsychotic was needed, a formulary medication was chosen. In the group in which an attempt was made to discontinue quetiapine ($n = 161$), the most commonly used alternatives were risperidone (20.5%) and perphenazine (11.8%). Risperidone, like quetiapine, is a second-generation antipsychotic that is available in a lower cost generic formulation. We suspect that the popularity of the first-generation antipsychotic perphenazine was related to its performance in the CATIE trial, in which it was found to be equivalent in clinical efficacy with both quetiapine and risperidone.¹⁷

Making quetiapine a nonformulary medication saved the NJDOC nearly \$1 million after accounting for the costs of alternative antipsychotics. There were no statistically significant increases in health care utilization in days in a higher level of care, days of increased observation status, or hospitalization outside of prison. We did not measure potential savings from reducing metabolic, neurologic, and other complications, but we suspect this number would be substantial, especially among the proportion of inmate patients formerly on quetiapine who no longer needed any antipsychotic medication.

Limitations of this study include those inherent in a retrospective chart review. A prospective approach is less practical in a correctional environment, and the study was not conceived until after the formulary change had already been decided by the Pharmacy and Therapeutics Committee. Including a randomized, prospective control group, although more scientifically rigorous, is not allowed by the New Jersey Administrative Code,²⁸ and randomization would have strongly interfered with the treating psychiatrists' clinical judgment. The authors were involved in the clinical management of some of the subjects. However, less than four percent of the subjects were receiving treatment from the authors during the period studied.

Comparisons of subjects for whom discontinuation of quetiapine was attempted with those in whom it was continued may have been biased toward no difference, in that the latter group was presumably more severely ill, given that the treating psychiatrist was unwilling to take the risk that the patient would decompensate without it. The duration of observation included in the comparison of outcome measures (a mean of 85.5 days when quetiapine was intended to be stopped) is relatively brief for a discontinuation study, and thus may underestimate the adverse consequences of quetiapine discontinuation.

This study did not have sufficient power to detect significant differences in several of our reported outcomes. The number of subjects was defined by the number of inmate patients prescribed quetiapine at the onset of the formulary change. Powering a study to detect clinical differences for uncommon events requires enrolling an impractically large population for a correctional setting. For example, even if this study had enrolled 2,000 patients on quetiapine, the exact power of a two-sided test to compare two binomials would have been only 45 percent for detecting a statistically significant difference in episodes requiring a higher level of care, given the low base rate (<10%) of such incidents. Although we cannot conclude that eliminating quetiapine from a medication formulary for a correctional system of our size has no risks, our study supports a finding that the risks are modest and stand in contrast to the benefits of substantially reducing the incidence of exposing patients to unneeded antipsychotic medication.

Quetiapine is subject to abuse and diversion, especially in a correctional environment, which is particularly troubling, given the known risks of antipsychotic medications. With the availability of more cost-effective medications, the risk-benefit ratio must be carefully considered before prescribing quetiapine in a prison setting. As generic forms of quetiapine become available, its abuse liability and other clinical risks will become more enduring reasons than cost for limiting its use in correctional settings.

Attempts to replicate these findings in other correctional systems would be welcomed. A follow-up study evaluating a longer period after quetiapine discontinuation would be appropriate. Future investigations may also focus on longer-term expected benefits such as reductions in medication-induced metabolic derangements.

Acknowledgments

The authors thank Deleca Barnes, PharmD (pharmacy consultation), Lisa Debilio, PhD (statistical consultation), Michael Gara, PhD (statistical consultation), Sophia Jordan (administrative support), and Jeff Mattes, MD (data collection).

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